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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/004,763	12/05/2001	Jon A. Wolff	MIRUS.003.06.2	8462

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Mark K. Johnson
PO Box 510644
New Berlin, WI 53151-0644

EXAMINER

KETTER, JAMES S

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 09/09/2003

Please find below and/or attached an Office communication concerning this application or proceeding.



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APPLICATION NO./ CONTROL NO.	FILING DATE	FIRST NAMED INVENTOR / PATENT IN REEXAMINATION	ATTORNEY DOCKET NO.
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EXAMINER

ART UNIT	PAPER
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0905

DATE MAILED:

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Commissioner for Patents

--See attached--

Office Action Summary	Application No. 10/004,763	Applicant(s) WOLFF ET AL.	
	Examiner James S. Ketter	Art Unit 1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 August 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) 1-8 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 9 and 10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 December 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
 If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
 * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

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Applicant's election without traverse of Group XIV, claims 9 and 10, in the paper filed 21 August 2003 is acknowledged.

Claims 1-8 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the paper filed 21 August 2003.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 9 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by The Merck Index, Tenth Edition (U, newly cited).

The Merck Index is cited merely to show that polylysine was well known in the art. At pages 1092 and 1093, entry number 7444 is to polylysine. Polylysine is a repeat of at least 32 monomers of lysine. The monomer of claim 9 is [A-B-C-B-], wherein A is the nucleic acid binding monomer, B is (among others) an aliphatic linker, and C is (among others) and ester or carbon-nitrogen single bond. Polylysine meets this formula, in that the side chain is a positively charged moiety which binds to DNA, and is thus A; the -C-C-N- backbone represents an

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aliphatic linker, and is thus B; the [-C-C-N]-[C-C-N-] linkage of the backbone of the first lysyl residue to the next lysyl residue represents either an ester or carbon-nitrogen single bond, and is thus C; the backbone of said next (second) lysyl residue is a second iteration of B; and, the [-C-C-N]-[C-C-N-] linkage of the backbone of said second lysyl residue to the third lysyl residue represents a second iteration of C; at which point the claimed monomer is repeated. Note that the presence of the side chain in the second lysyl residue is not excluded by the open language of the claim, i.e., "comprising". The monomer of claim 10 is similarly anticipated, differing only in that the second occurrence of C is not necessarily present.

Claims 9 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Schatz et al. (A, newly cited).

At the paragraph bridging columns 13 and 14, Schatz et al. teaches a polypeptide comprising a Lac repressor segment (the headpiece, which is the DNA binding portion) fused to a second Lac repressor headpiece. As set forth in the rejection, above, of the claim over the structure of polylysine, the backbone of a polypeptide reads on parts -B-C-B-C- or -B-C-B- of the claimed polymers. The Lac repressor headpieces represent A of the claimed polymers. At column 14, lines 13-15, it is taught that 3, 4, 5 or more copies of the headpiece region may be present.

Claims 9 and 10 are rejected under 35 U.S.C. 102(e) as being anticipated by Arnold, Jr. et al. (B, newly cited, hereinafter "Arnold et al.").

At column 6, around lines 49-54, compound II is set forth, as a non-nucleotide monomer from which to construct a polymer. At column 5, lines 11-18, it is taught that a polymer could be constructed having interspersed hybridizable nucleotides as one block and non-nucleotide monomers as a second block. Alternatively, at column 4, line 55, it is taught that an intercalating compound may be attached to the backbone. Compound II may be restated as a backbone with the following features: [-C1-O1-C2(-ligand)-O2-P-O3-] or [-C1-O1-C2(-ligand)-O2-P-N-], wherein the ligand is a side chain from C2. Thus, the polymer of claim 9 is met as follows: the hybridizable nucleotide stretch or the intercalating molecule, linked to C2, represents A; C1 of the second monomer, as an aliphatic carbon, represents the first occurrence of B; the linkage of second monomer C1 to second monomer C2 through second monomer O1 is an ether linkage, and thus represents the first C; C1 of the third monomer represents the second occurrence of B; and the linkage of third monomer C1 to third monomer C2 through third monomer O1 is the second occurrence of C; all of which represent a single monomer as represented in the claims. Alternatively, the phosphoester bonds on either side of the phosphorus, which are thus ester bonds, in the second and third monomers would read on first and second C. Still another alternative, involving the second form of compound II, would see the N-C1 bond of the first to second, and second to third monomers as first C and second C, respectively. The monomer of claim 10 is similarly anticipated, differing only in that the second occurrence of C is not necessarily present.

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The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 9 and 10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 9 recites “nucleic acid-binding monomer including positively charged organic monomers”. However, it is not clear whether the claim is limited to said monomer being a positively-charged organic monomer, as the meaning of “including” in this context is not clearly limiting.

Claims 9 and 10, at the next-to-last line, repeats “carbon-nitrogen single bond”, thus rendering the claim confusing.

Claim 10, recites “nucleic acid-binding monomer that includes positively charged organic monomers”. However, it is not clear whether the claim is limited to said monomer being a positively-charged organic monomer, as the meaning of “that includes” in this context is not clearly limiting.

Claim 10, at the next-to-last line, uses a comma instead of “and” to separate the ultimate and penultimate members of the list, and is thus grammatically incorrect.

Certain papers related to this application may be submitted directly to the Examiner by facsimile transmission at (703) 746-5155. The faxing of such papers must conform with the

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notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993)(see 37 CFR ' 1.6(d)). To send the facsimile to the Art Unit instead, the Art Unit 1636 Fax number is (703) 305-7939. NOTE: If Applicant does submit a paper by fax to this number, the Examiner must be notified promptly, to ensure matching of the faxed paper to the application file, and the original signed copy should be retained by Applicant or Applicant's representative. (703) 308-4242 or (703) 305-3014 may be used without notification of the Examiner, with such faxed papers being handled in the manner of mailed responses. Applicant is encouraged to use the latter two fax numbers unless immediate action by the Examiner is required, e.g., during discussions of claim language for allowable subject matter. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the Examiner with respect to the examination on the merits should be directed to James Ketter whose telephone number is (703) 308-1169. The Examiner normally can be reached on M-F (9:00-6:30), with alternate Fridays off.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Remy Yucel, can be reached at (703) 305-1998.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

Jsk
September 5, 2003



JAMES KETTER
PRIMARY EXAMINER